



DEPARTMENT OF HEALTH AND HUMAN SERVICE

94755d
Public Health Service

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

May 20, 2004

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2004-12

Mr. Henry M. Nelson, President
Nelsons Premix Service, Inc.
131 Old Creek Road
Storm Lake, IA 50588

Dear Mr. Nelson:

An inspection of your veterinary health products sales facility was conducted on March 2-3, 2004, by a representative of our office. This inspection revealed your firm is purchasing and further distributing prescription drug products for animal use. Under Section 503(f)(1)(C) of the Federal Food, Drug and Cosmetic Act, the dispensing of a prescription drug other than by or upon the lawful written or oral order of a licensed veterinarian results in the drug being misbranded. Examples of prescription drugs your firm is dispensing without an order from a licensed veterinarian include: A180, Baytril, Naxcel, Oxytocin, GentaVed, Amoxicillin (approved for human use), Lutalyse, NuFlor, Cephalexin Suspension (approved for human use), Excenel, and Dexamethasone.

You are also selling new animal drugs which are misbranded under the Act because they do not have adequate directions for use. According to 21 CFR 201.5, "adequate directions for use" means adequate directions under which the layman can use a drug safely and for the purposes for which it was intended. Such adequate directions for use by laypersons cannot be written for prescription drugs because the drugs can only be used safely at the direction of, and under the supervision of, a licensed veterinarian. Therefore, you are selling prescription drugs for veterinary use, which are misbranded with the meaning of Section 502(f)(1) of the Act.

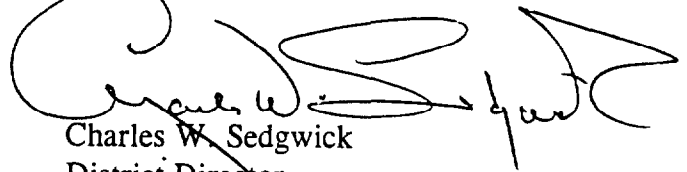
You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

This is not intended to be an all-inclusive list of violations that may be present in your firm. You have a responsibility to insure that all drugs handled by your firm comply with all legal and regulatory requirements.

Warning Letter
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Nelsons Premix Service, Inc.
May 20, 2004
Page 2

It is necessary for you to take action on this matter now. Let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. Your reply should be sent to Nadine Nanko Johnson, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick", with a large, stylized flourish extending to the right.

Charles W. Sedgwick
District Director
Kansas City District